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10/734,274	12/15/2003	Karel Hero Mulder	2005-1021.	1503

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EXAMINER

NGUYEN, HUONG Q

ART UNIT PAPER NUMBER

3736

DATE MAILED: 12/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/734,274

Applicant(s)

MULDER, KAREL HERO

Examiner

Helen Nguyen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 December 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. This Office Action is responsive to the amendment filed 8/9/2006. Amendments to the specification overcome the previous specification and some of the previous drawing objections. Claims 1-22 are cancelled. **Claims 23-42** are new and pending.

Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore the urine indicator means of **Claims 36-38**, and the flow indicator means and time duration indicator means embodied as separate measuring devices between the two foil sheets of **Claims 31 and 42** respectively must be clearly shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will

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be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

3. **Claim 37** is objected to for using the phrase “in particular” which renders said claim indefinite because it is not clear whether the instant case is claimed or not.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

5. **Claims 31 and 42** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In the instant case, both claims refer to means comprising a separate measuring device enclosed between the two foil sheets. After reading p.4 line 7-10 and p.10 line 20-22 of the specification, it is still unclear how the above-mentioned means are formed separate from the foil sheets. It is also noted that the particulars of said claims have not been clearly shown in the submitted drawings, as objected to above.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. **Claims 23** is rejected under 35 U.S.C. 102(e) as being anticipated by Suydam (US Pub No. 20020193762). Suydam discloses a urological instrument for assessing a urine flow comprising a receiving member (34) for the urine flow and comprising flow indicator means (30) capable of assessing at least a magnitude of the urine flow, in which, at least in a ready to use state, the receiving member is in open liquid communication with a urine guide (28) and an inlet of the indicator means, all best seen in Figure 2, characterized in that the instrument is embodied as a disposable article which is formed substantially from flexible material (i.e. plastic), in that the instrument is in a folded position in a storage state (§0030), components of the instrument lying at least substantially folded onto each other, best seen in Figure 6, in that the instrument is in a straightened position in the ready to use state, as shown in Figure 2, said components of the instrument lying at least substantially in line with each other, in that the receiving member (24) has a relatively compact storage state and an expanded ready to use state (§0031, 0040), in that the receiving member is designed and adapted to be brought manually from its storage state to its ready to use state, and that the receiving member is open on at least one side and comprises a cavity for receiving the urine flow therein, at least in its ready to use state, as best seen in Figure 2.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. **Claims 24-28 and 39-41** are rejected under 35 U.S.C. 103(a) as being unpatentable over Suydam in view of Dye (US Pat No. 3831446)

10. In regards to **Claim 24**, Suydam discloses the invention described above including a collection device (26) that at least during use is in open communication with the urine guide (28) on an end opposite the receiving member (34), best seen in Figure 2, and the collection device is expandable from a relatively compact storage state to an expanded position of use. However, Suydam does not disclose said collection device provided with a closing member having a normally closed position. Dye teaches the inclusion of a closing member, referred to as "valve means" (64), normally in the closed position, to allow controlled passage of fluid to an analogous collection device (24) (Col.5: 12-15). Therefore, it would have been obvious to one of ordinary skill in the art to modify the collection device of Suydam to include a closing member normally in the closed position, as taught by Dye, to provide a means for allowing the controlled passage of fluid from the collection device.

11. In regards to **Claim 25**, Suydam disclose the collecting device (26) is connected to an outlet of the flow indicator means (30), best seen in Figure 4.

12. In regards to **Claim 26**, Suydam discloses the collecting device (26) comprising a collecting bag, best seen in Figure 2.

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13. In regards to **Claim 27**, Suydam discloses the invention above but does not disclose the collecting device (26) provided with volume indicator means for a urine volume received therein. Dye teaches the use of volume indicator means, referred to as “graduated indicia” (74) (Col.5, line 45-47), to provide an effective means of determining total volume of urine collected. Therefore, it would have been obvious to one of ordinary skill in the art to modify the invention of Suydam to include volume indicator means, as taught by Dye, to improve the device by providing an effective means to determine total volume.

14. In regards to **Claim 28**, Suydam discloses that in the storage state, at least one of the receiving member (34) and the collecting device (26) is capable of covering the urine guide (28) on one side of the flow indicator means (30).

15. In regards to **Claim 39-41**, Suydam discloses the invention above but does not disclose time duration indicator means. Dye teaches the use of time duration indicator means, referred to as “indicia” (62) and comprising a reservoir, referred to as “container” (24), which at least during use is in open communication via a defined passage opening, referred to as “chamber” (34) situated at least close to an inlet of a flow indicator means (38), with the urine flow (Col.4, line 42-52), wherein said reservoir is provided with volume indicator means, referred to as “graduated indicia” (74), for a urine volume received therein (Col.5, line 43-47), said time duration indicator means for determining a time duration of the urine flow (Col.5, line 2-7). Therefore, it would have been obvious to one of ordinary skill in the art to modify the invention of Suydam to include time duration indicator means with the structure described above, as taught

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by Dye, to improve the device by including a means for determining a time duration of the urine flow.

16. **Claims 29-31 and 42** are rejected under 35 U.S.C. 103(a) as being unpatentable over Suydam in view of McWhorter (US Pat No. 3831453), further in view of Persson (US Pat No. 3928875). Suydam discloses a urological instrument formed from flexible material, as explained above but does not disclose the flexible material comprising two foil sheets hermetically to each other on a mutual contact surface, at least partially forming one or more components of said device, wherein said components include the receiving member, the urine guide, the flow indicator means, and the collecting device.

17. McWhorter discloses a urological device formed from two flexible plastic sheets closed by heat, thus constituting a hermetic seal, forming one or more components of the device, in the instant case, a collection bag, referred to as "bag" (Col.1, line 51-61), for more accurate measurement of urine output (Col.1, line 22-23). However, McWhorter does not disclose the two flexible sheets as foil. Persson discloses a urine collector formed of flexible foil material for cheap manufacture and thus, disposability (Col.1, line 9-13).

18. Therefore, it would have been obvious to one of ordinary skill in the art to make the urological device of Suydam, using two sheets hermetically forming one or more components of said device, as taught by McWhorter, wherein said sheets are foil sheets, as taught by Persson, to effectively manufacture an accurate device while keeping costs cheap for economic disposal. As integral manufacture of the instrument components (such as the receiving member, urine guide, collecting device) is possible, it would then also be obvious to manufacture specific components

of said urological device as separate from said foil sheets, for example, flow indicator means or time duration indicator means, for reasons such as better precision, as such methods of manufacture are obvious in view of McWhorter and known to those skilled in the art.

19. **Claim 32** is rejected under 35 U.S.C. 103(a) as being unpatentable over Suydam in view of Griffitts (US Pat No. 2856932). Suydam discloses a urological instrument but does not disclose said device provided with an irreparable breakable seal. Griffitts discloses a urethral catheter and bag maintained in a storage state, wherein the device is opened from a storage state to a ready-to-use state by breaking an irreparable breakable seal, referred to as “flag” (36), wherein the presence of an unbroken seal is an effective indicator of device sterility, best seen in Figures 2, 3, 5 (Col.3, line 56-62, 71-74). Therefore, it would have been obvious to one of ordinary skill in the art to incorporate a similar irreparable breakable seal as taught by Griffitts into the urological instrument disclosed by Suydam, for holding said instrument in the storage state, wherein the breaking of said seal brings the instrument into ready-to-use state, as an effective mean to indicate device sterility.

20. **Claim 33** is rejected under 35 U.S.C. 103(a) as being unpatentable over Suydam in view of Oxley (US Pat No. 5423792). Suydam discloses a urological instrument but does not disclose recording means arranged on an outer side for manual recording of indicator values determined with said device. Oxley discloses a fluid collection container having a recording means or identification element, in particular, a “writeable area” (42), for manual recording of information (Col.6, line 62-66). Therefore, it would have been obvious to one of ordinary skill in the art at

the time the invention was made to include a similar recording means as taught by Oxley into the urological device of Suydam to provide a means to effectively classify and identify said device.

21. **Claims 34-35** are rejected under 35 U.S.C. 103(a) as being unpatentable over Suydam in view of Oxley (US Pat No. 5423792), further in view of LeVeen et al (US Pat No. 4532936).

Suydam as modified by Oxley discloses a urological instrument with a recording means but do not disclose the means as a removable self-adhesive label. LeVeen et al disclose urological data printed on self-adherent paper for ease of information transfer (Col.5, line 8-10). Therefore, it would have been obvious to one of ordinary skill to modify the recording means of Oxley to be a self-adhesive label, as taught by LeVeen et al, and incorporate that into the device of Suydam, to provide ease of urological information recording and transfer. Similarly, it would have been obvious to arrange such label at a position on said urological device such as at the position of a flow indicator means while leaving a transparent window for display of information.

22. **Claims 36-38** are rejected under 35 U.S.C. 103(a) as being unpatentable over Suydam in view of Hiruta et al (US Pat No. 5111539). Suydam discloses the invention above but does not disclose urine indicator means in the form of a flexible carrier, such as paper, used to determine at least one component of urine composition, wherein said composition comprises glucose, bilirubin, ketones, blood, proteins, urobilinogen, nitrites, leucocytes, and acids. Hiruta et al disclose a urological device comprising urine indicator means, referred to as "urine test paper piece" (6), placed in a urine path to as an effective method to determine at least one component of urine composition such as glucose, urobilinogen, or blood (Col.6, line 26-37). Therefore, it

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would have been obvious to one of ordinary skill in the art to improve the urological device of Suydam to include a urine indicator means in the form of a paper carrier to determine a desired component of urine composition, as taught by Hiruta et al, to provide an effective method of obtaining other essential urological data from a urine sample, enabling said urological instrument to be more complete and useful.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helen Nguyen whose telephone number is 571-272-8340. The examiner can normally be reached on Monday - Friday, 8 am - 5 pm.

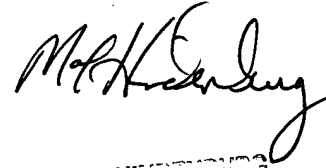
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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HQN

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